

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION

THIS DOCUMENT RELATES TO:

*Mayor Farris Burton, on Behalf of the
Town of West Hamlin v. Purdue Pharma
L.P., et al.*, Case No. Unassigned
(Transfer Order dated 8/1/2018, MDL
2804 Dkt. No. 2133)

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**DEFENDANT MCKESSON CORPORATION'S NOTICE REGARDING
POTENTIAL NONPARTY FAULT UNDER W. VA. CODE § 55-7-13d**

Defendant McKesson Corporation (“McKesson”), by counsel, hereby submits its notice of nonparty fault pursuant to W. Va. Code § 55-7-13d. West Virginia Code § 55-7-13d(a)(2) states that “[f]ault of a nonparty shall be considered . . . if a defending party gives notice no later than one hundred eighty days after service of process upon said defendant that a nonparty was wholly or partially at fault.”¹

Plaintiff seeks to hold multiple wholesale pharmaceutical distributors responsible for an opioid epidemic that Defendants, much less any one of them, could not possibly have caused. Plaintiff also seeks to hold Defendants responsible not only for the “opioid epidemic” but also for heroin abuse in The Town of West Hamlin. (*See, e.g.*, Compl. ¶¶ 108–111.)

Wholesale pharmaceutical distributors, such as McKesson, merely distribute prescription medications from various manufacturers to pharmacies. Distributors have no role in manufacturing

¹ Given this statutory language, McKesson is filing its Notice at this time in an abundance of caution.

or promoting opioids to physicians; they have no role in determining how opioids should be or are prescribed; and they have no role in how pharmacists dispense opioids. Distributors simply do not set and enforce quotas that limit the amount of opioids shipped to licensed pharmacies. And distributors have no law enforcement duty or authority over opioids after a licensed pharmacy receives its bulk shipments.

Litigation of Plaintiff's claims, then, necessarily involves all persons and entities who were involved in manufacturing, prescribing, dispensing, regulating, and using opioid medications and those involved in the illegal production, sale, and use of heroin and other illegal drugs in the county. If anyone could be apportioned legal liability related to a drug abuse epidemic, nonparties necessarily would be at fault for the injuries alleged in Plaintiff's Complaint.

This case has been transferred to the Opioid MDL and was not selected as an initial bellwether, so the parties have not begun discovery. Thus, at this time, McKesson cannot specifically identify nonparties that could be at fault for the injuries alleged in Plaintiff's Complaint. McKesson therefore identifies the categories of individuals and entities who may be nonparties at fault based on their legal obligations. This is the "best identification of the nonparty which is possible under the circumstances." W. Va. Code § 55-7-13d(2). McKesson will supplement this notice once the specific identities of nonparties with potential fault because they can be shown to have violated their legal obligations are discovered.

I. Pharmacies and Pharmacists

McKesson distributes controlled substances only to pharmacies that hold valid licenses from the Drug Enforcement Administration (the "DEA") and in West Virginia, the Board of Pharmacy (the "WVBOP"). Individual pharmacists working at those pharmacies also must be DEA-registered and licensed by the WVBOP. Pharmacies cannot dispense a controlled substance other than in response

to a valid prescription from a licensed doctor, and pharmacists have a “corresponding responsibility” not to fill a prescription that the pharmacist knows was written for other than a medically necessary purpose.²

If Plaintiff has been damaged as a result of prescription opioid and heroin abuse, as Plaintiff alleges, it would be, in part at least, because pharmacies dispensing controlled substances to The Town of West Hamlin residents were not complying with their legal obligations when dispensing those controlled substances. Plaintiff, however, fails to identify any pharmacy or pharmacist that allegedly failed to comply with its legal obligations when dispensing controlled substances to The Town of West Hamlin residents. Plaintiff also fails to identify any pharmacy that placed suspicious orders that McKesson then allegedly failed to identify and report, although placing suspicious orders is not unlawful and suspicious orders do not necessarily indicate unlawful diversion. Once any pharmacies and their pharmacists are shown to have dispensed controlled substances to The Town of West Hamlin residents in violation of their legal obligations, McKesson will supplement this notice with their identities.

II. Prescribing Practitioners

² Although the primary “responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner,” DEA regulations place a “corresponding responsibility” on the “pharmacist who fills the prescription.” 21 C.F.R. § 1306.04(a); *see* W. Va. C.S.R. § 15-2-7.4.1 (same). The DEA requires “pharmacists [to] use common sense and professional judgment,” which includes paying attention to the “number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment,” the number of doctors writing prescriptions, and whether the drugs prescribed have a high rate of abuse. *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730 (DEA Feb. 9, 1990). DEA requires that a pharmacist refuse to dispense when a prescription raises suspicion and its propriety cannot be verified. *Id.*

Prescribing practitioners must be registered with the DEA and licensed by a State medical board. A prescribing physician can write an opioid prescription only for a medically necessary purpose after examining the patient.³

If Plaintiff has been damaged as a result of prescription opioid and heroin abuse, as Plaintiff alleges, it would be, in part at least, because prescribing practitioners wrote prescriptions for controlled substances to The Town of West Hamlin residents for other than a medically necessary purpose. Plaintiff, however, fails to identify any prescribing practitioner that allegedly failed to comply with its legal obligations when writing prescriptions for controlled substances to The Town of West Hamlin residents. Once any prescribing practitioner is shown to have written prescriptions for controlled substances to The Town of West Hamlin residents in violation of the practitioner's legal obligations, McKesson will supplement this notice with the practitioners' identities.

III. Individuals Involved in Illegal Drug Sales

If Plaintiff has been damaged as a result of prescription opioid and heroin abuse, as Plaintiff alleges, it would be, in part at least, because individuals have been involved in illegal sales or sharing of opioid medications, heroin, and/or other illegal drugs within the county. Plaintiff, however, fails to identify any individual involved in illegal drug sales and sharing in the county, and, furthermore, it may not be possible to identify all such individuals. To the extent that such individuals are identified in the course of discovery, McKesson will supplement this notice with their identities.

³ Federal and state regulations require that prescriptions for controlled substances "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); W. Va. C.S.R. § 15-2-7.4.1 ("issue a prescription for a controlled substance for a legitimate medical purpose in the usual course of his or her professional practice"). Also, it is unlawful for patients to deceive doctors to obtain opioid prescriptions. *See* W. Va. Code § 60A-4-403(a)(3) (making it unlawful to knowingly or intentionally "obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge").

IV. Pharmaceutical Manufacturers

To the extent the opioid medications distributed by McKesson to pharmacies within the county were improperly dispensed because of inadequate instructions or warnings or of false or misleading advertising and promotion by the manufacturers, pharmaceutical manufacturers' actions or omissions contributed to the harms alleged by Plaintiff. Plaintiff, however, fails to identify any pharmaceutical manufacturer whose opioid medications carried inadequate instructions or warnings or which the manufacturer promoted through false or misleading advertising or other forms of promotion. To the extent that such pharmaceutical manufacturers are identified in the course of discovery, McKesson will supplement this notice with their identities.

V. Nonparty Wholesale Pharmaceutical Distributors

McKesson is only one of many wholesale distributors that distribute medications to pharmacies within the county. To the extent that excess controlled substances were distributed to the county (*i.e.*, distributed in violation of a distributor's legal obligations, although those obligations do not run to Plaintiff), as alleged by Plaintiff, those controlled substances were distributed, at least in part, by wholesale pharmaceutical distributors other than McKesson. McKesson, however, does not have access to the DEA's ARCOS database, which contains the identities of all pharmaceutical distributors who distributed controlled substances into The Town of West Hamlin. McKesson also does not have access to other evidence of potential excess distribution by any other distributor. It is possible that Plaintiff has not named as defendants all wholesale pharmaceutical distributors of the many who may have allegedly distributed excess controlled substances into the county. To the extent that nonparty pharmaceutical distributors shipped excess amounts of controlled substances into the county in violation of their legal obligations are identified in the course of discovery, McKesson will supplement this notice with their identities.

VI. Federal, State, and Local Government Entities

The Food and Drug Administration (the “FDA”) comprehensively regulates prescription drugs in the United States. The DEA, through delegated authority, administers and enforces the federal Controlled Substances Act and its implementing regulations, including establishing annual production quotas for schedule II controlled substances, such as opioid medications. The WVBOP administers and enforces the West Virginia Uniform Controlled Substances Act and its implementing regulations. The WVBOP also administers the State’s Prescription Drug Monitoring Program to which pharmacies and prescribing practitioners, but not distributors, report and have access. The West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, and the West Virginia Board of Examiners for Registered Professional Nurses are responsible for licensing and regulating practitioners who prescribe controlled substances to The Town of West Hamlin residents. The West Virginia State Police, the The Town of West Hamlin Sheriff’s Department, and the police departments of municipalities in The Town of West Hamlin are responsible for enforcing the laws related to illegal drug sale and use. The Bureau for Medical Services (“BMS”) of the West Virginia Department of Health and Human Resources administers the West Virginia Medicaid Program with the goal “to improve the quality of care and health outcomes for West Virginia Medicaid members by assuring that the medications prescribed for them are appropriate, *medically necessary*, and not likely to result in adverse medical effects” (emphasis added). BMS requires, *inter alia*, that prior authorization be obtained through the Rational Drug Therapy Program (the “RDT”) of the WVU School of Pharmacy before opioids prescribed for chronic pain are reimbursable. The West Virginia Public Employees Insurance Agency (the “PEIA”) likewise requires prior authorization through the RDT for certain opioid medications before the medications are reimbursable. As the PEIA’s website states, “[a]ll prior authorization requests must

be reviewed annually.” Other federal and state programs that provide reimbursement for opioid medications may similarly seek to ensure the medical necessity of prescription opioids.

The failure of these federal, state, and local government entities, individually and/or collectively, to take timely and effective enforcement action, caused or contributed to the harms alleged by Plaintiff. Accordingly, McKesson identifies any federal, state, or local government entity that failed to take timely and effective enforcement action related to the unlawful manufacture, promotion, sale, dispensing, prescribing, and/or diversion of controlled substances, or related to the illegal sale and use of drugs in The Town of West Hamlin as nonparties at fault.⁴

Reservation of Right to Amend After Discovery

Discovery has not yet begun in this case. McKesson therefore reserves its right to amend this notice to add any nonparties that may have whole or partial fault for Plaintiff’s alleged harms and supplement this list with the names and addresses of the nonparties at fault once discovery reveals the specific identities of those parties.

August 7, 2018

/s/ Geoffrey E. Hobart

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⁴ Governmental entities may be “wholly or partially at fault” under W. Va. Code § 55-7-13d, whether or not they enjoy immunity from suit or otherwise cannot be named as a party defendant.

CERTIFICATE OF SERVICE

I, Geoffrey Hobart, hereby certify that on this the 7th day of August, 2018 the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Geoffrey E. Hobart
Geoffrey E. Hobart